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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,111	11/05/2001	Gerard Bernard O'Beime	PA-0060	7469

7590 06/15/2004
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EXAMINER

GABEL, GAILENE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/992,111	Applicant(s) O'BEIRNE ET AL.	
	Examiner Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 and 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 1, claims 1 and 5-13, with traverse, filed on 5/29/04 is acknowledged and has been entered. Claims 2-4 and 14-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1-19 are pending. Claims 1 and 5-13 are under examination.

Traversal of Restriction Requirement

2. Applicant's traversal is on the basis of the relationship between Inventions I and II; specifically, that Inventions I and II are quite similar and related since the distinction therebetween only exists in the addition of a test compound into the method of Invention II. Applicant submits that the processes of Inventions I and II should have the same modes of operation and the same effects and argues that the inclusion of a test compound does not change the process involved in the claims. Applicant thus concludes that examining claims 1-13, including both Inventions I and II would not pose undue burden on the Examiner.

Applicant's argument is not persuasive because restriction requirements are set forth for reasons of patentable distinction between each independent invention having distinct structural or manipulative requirements, i.e. incorporation of test compound in Invention II, to thus warrant separate classification and search. Literature search for

each process is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive. The record set forth in the previous restriction requirement clearly indicated that the delineated inventions are in fact patentably distinct each from the other or independent from the other. The requirement is still deemed proper and is therefore made FINAL for reasons of record.

Specification

3. The use of the trademark CYTODEX and SEPHADEX has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, and 5-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step i) is vague and indefinite in reciting, "cells adhering to support particles" because it is unclear if Applicant intends for specific cell populations to form a complex, i.e. attached or bound or adhered, with the support particles. See also step ii).

Claim 1, step i) is confusing because it is unclear what functional cooperative relationship exists between "the one or more different populations of cells" and "the support particles" upon which the cell populations adhere. First, it is unclear how the different populations of cells differentially and specifically, adhere or attach to the support particles to thus obtain different populations of cells since it appears that Applicant intends for the different populations to be subsequently separated into separate reaction vessels in step ii). Please clarify.

Claim 1, step i) is vague and indefinite in reciting, "support particles ... being adapted for cell growth" because it is unclear how the support particles are modified or adapted to support cell growth.

Claim 1, step iii) is ambiguous in reciting, "said radiolabeled reagent to become associated with said cells" because it is unclear what Applicant intends to encompass in reciting "associated" as used in the claim, i.e. bind, attach, adjacent, etc. See also claim 7.

Claim 1, step iv) lacks clear antecedent basis in reciting, "the scintillant particles".

Claim 5 is indefinite because it is unclear as to whether "the different samples of each of said cells" still comprise different populations of cells.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1 and 5-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Jessop (US Patent 6,524,786).

Jessop discloses scintillation proximity assays performed in multiwell plates wherein a charge-coupled device (CCD) is used in a detection step to image cellular processes in living cells (see Abstract, column 2, line 59 to column 3, line 11, and column 4, lines 4-37). Jessop teaches providing one or more different populations of living cells which are attached to support particles capable of cell growth (particulates or beads) and carrying a scintillant substance (phosphor). In practice, Jessop teaches introducing the cells attached to scintillant particles in a medium, to massive surfaces such as separate vessels or wells of a microtiter plate (see column 3, lines 12-25 and lines 52-66 and Example 9). Thereafter, radioisotope-labeled reagent is added to the

Art Unit: 1641

wells so as to monitor uptake (association) of the radioisotope by the cells in real time or dynamic mode. The radioisotopes include ^3H , ^{125}I , ^{14}C , ^{35}S , ^{56}Ca , ^{33}P , ^{32}P , ^{55}Fe , ^{86}Rb , ^{109}Cd , and ^{51}Cr (see column 3, lines 45-51). Cellular processes are measured by detecting light emission from the scintillant support particles as caused by the radioactive decay of the radioisotope label (see column 3, lines 26-44). The cellular processes tested include receptor binding assay, uptake, and biochemical response. Different concentrations of radioisotope label are incubated with different samples of cells in reaction vessels (see column 3, lines 64-67 and Examples 1, 6, 7 and 9). Jessop provides that detection step may be performed by scintillation counting (see column 1, lines 47-60).

6. No claims are allowed.

Remarks

7. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Cook (US Patent 5,989,854) provides an SPA method of studying cellular processes using vessels of a multiwell plate wherein measurement is performed in real time (see column 5).

Cook (Drug Discovery Today, vol. 1 (7): 287-294 (1996)) teaches SPA with applications in high throughput screening technology.

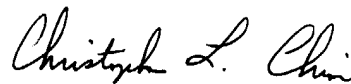
Dean (WO 96/19739) discloses specialized beads which advantageously support cell growth for application in high throughput multiwell assay systems.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
June 7, 2004



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